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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,108	02/13/2002	Christoph Pedain	SCHWP0156US	6951

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RENNER, OTTO, BOISSELLE & SKLAR, LLP
Nineteenth Floor
1621 Euclid Avenue
Cleveland, OH 44115-2191

EXAMINER	
EDWARDS, PATRICK L	
ART UNIT	**PAPER NUMBER**
2621	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,108	PEDAIN ET AL.	
	Examiner	Art Unit	
	Patrick L. Edwards	2621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02-13-2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

2. As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 11, 12, 20, and 21 are rejected under 35 U.S.C 101 as being directed to non-statutory subject matter. As currently written, claims 11 and 20 recite purely functional descriptive material, which is non-statutory. This problem can be easily remedied by amending the preamble of the claims to recite "A computer program, stored on a computer readable medium, comprising:"

Claims 12 and 21 are rejected because of their dependency on claims 11 and 20, respectively.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9 and 10 contain many reference to terms that lack antecedent basis.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-16, 20, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemelson (USPN 5,919,135).

Regarding claim 1, Lemelson discloses a method for planning an infusion, wherein patient data are captured and the infusion to be carried out is planned using said patient data (Lemelson col. 4 lines 15-26: The refence describes capturing patient data and planning an infusion (i.e. the injection into a patient).).

Regarding claim 2, Lemelson discloses the method as set forth in claim 1, wherein at least one infusion device is positioned using said patient data (Lemelson col. 4 lines 41-46).

Regarding claim 3, Lemelson discloses the method as set forth in claim 2, wherein said infusion device is positioned on a body with respect to the infusion location and/or to the depth of penetration into said body (Lemelson col. 4 lines 41-46: The reference describes that a catheter (i.e. infusion device) is positioned on a body with respect to the infusion locaton).

Regarding claim 4, Lemelson discloses the method as set forth in claim 1, wherein said patient data are captured by a magnetic resonance method (MRI), a computer tomography method (CT), an x-ray method or an ultrasound method (Lemelson col. 4 lines 10-15).

Regarding claim 5, Lemelson discloses the method as set forth in claim 1, wherein patient parameters are obtained from said captured patient data and are used for planning said infusion (Lemelson col. 4 lines 45-65: The reference describes determining patient parameters—such as tissue structure and blood flow—are used for planning the infusion).

Regarding claim 6, the method as set forth in claim 5, wherein information on the tissue structure, tissue density, blood flow and/or metabolic properties of said tissue is used as said patient parameters.

Regarding claim 7, Lemelson discloses the method as set forth in claim 1, wherein parameters of said infusing medium, defining chemical, biological and/or physical properties of said infusing medium, are used for planning said infusion (Lemelson col. 13 line 25 – col. 14 line 5 and elsewhere in the specification: Lemelson describes different infusing mediums with different chemical, biological, and physical properties. These parameters are used to plan the infusion (i.e. determine the amount of medium to be injected, etc.)).

Regarding claim 8, Lemelson discloses the method as set forth in claim 1, wherein catheter parameters are used for planning said infusion (Lemelson col. 3 lines 45-50, col. 11 lines 5-30 and elsewhere: The reference both describes determining the position of the catheter (which inherently requires knowing physical properties of the catheter, such as its length), and manipulating the size of the catheter itself—which also requires knowledge of the physical properties of said catheter).

Regarding claim 9, all of the limitations have been addressed above.

Regarding claim 10, Lemelson discloses the method as set forth in claim 1, wherein a target volume and/or distribution of infusing medium in the patient is pre-set, and the catheter parameters and parameters of said infusion medium required for this are determined on the basis of these (Lemelson col. 12 line 25 – col. 13 line 8: The reference describes that when a target volume (i.e. a location for injection) is known, that the catheter parameters (i.e. a second catheter) and parameters of the infusing medium (i.e. nitrous oxide, hydrogen, etc.) are determined on the basis of what is known.).

Regarding claim 13, all of the limitations have been addressed above.

Regarding claim 14, Lemelson discloses such a navigation system (Lemelson col. 4 lines 40-45).

Regarding claims 15 and 16, all of the limitations have been addressed above.

Regarding claims 11, 12, 20, and 21, Lemelson discloses a computer system for performing the steps of the method of claim 1 (see Lemelson Fig. 1). Inherent in this computer system is a computer readable medium storing the steps to perform the method.

9. Claims 15-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Kucharczyk et al. (USPN 6,026,316).

Regarding claims 15 and 16, Kucharczyk discloses planning an infusion in accordance with a method wherein patient data are captured and the infusion to be carried out is planned using said patient data (Kucharczyk Figure 7: The patient data is determined from the captured MR image. The infusion is then performed.).

Regarding claim 17, Kucharczyk discloses the method as set forth in claim 15, wherein the actual infusion data are compared with the planned infusion data (Kucharczyk Figure 7: The refernce describes superimposing drug delivery map (i.e. actual infusion data) on the anatomic map of target tissue (i.e. planned data). This is a comparison operation.).

Regarding claim 18, Kucharczyk discoses the method as set forth in claim 17, wherein deviations between said planned and said actual infusion data are determined (Kucharczyk Figure 7 with col. 21 line 49 – col. 22 line 32).

Regarding claim 19, the method as set forth in claim 18, wherein the infusion parameters are corrected based on said determined deviations (Kucharczyk Figure 7 with col. 21 line 49 – col. 22 line 32).

Regarding claims 22 and 23, Kucharczyk discoses a device for performing the method of claims 15 (see Kucharczyk, generally).

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick L Edwards whose telephone number is (571) 272-7390. The examiner can normally be reached on 8:30am - 5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Mancuso can be reached on (571) 272-7695. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick L Edwards Art Unit 2621

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ANDREW W. JOHNS
PRIMARY EXAMINER